Remarks

This Amendment is submitted in response to an Office Action mailed on September 1, 2005. By this amendment, Claim 1 has been amended, Claims 39-49 have been cancelled and Claims 50-59 have been added. Thus, upon entry of this amendment, Claims 1-9 and 50-59 will be in the present application. The amendments made herein to the claims do not incorporate new matter into the application as originally filed. Support for the amendments can be found in the drawings and throughout the specification.

As an initial matter, it should be noted that the present invention as now amended is directed to a delivery device for introducing a substance directly at least via a continuously open side-port into selected region(s) of the skin at pressures less than 5psi. Such systems are desirable in order to accurately place a deposit of substance within the skin as well as to reduce the delivery pressure to the skin. The side-ported device may be supplied from a removable external reservoir, such as a syringe. Additionally, it is desirable to have a system that is able to selectively deliver a substance to the skin such that there would be reduced leakage from both the skin and the device when the system is pressurized from the connection of needle to reservoir. The device of the instant application includes a needle and at least one outlet positioned perpendicular to the insertion axis of the needle. The needle has a specific length and outlet placement for directing said substance under pressure from the reservoir into the skin, as well as optionally between 30 and 34 gauge. As has been discovered, the threshold pressures involved with delivery to the skin are much higher than the pressures to deliver to other tissues, and therefore a system according to the present invention, capable of lowering delivery pressures, is required to deliver to the skin without adverse effects such as leakage from the connections to the device.

Applicant's Response to the 37 C.F.R. 1.75(d) Objection to the Specification and 37 C.F.R. 1.83 Objection to the Drawings

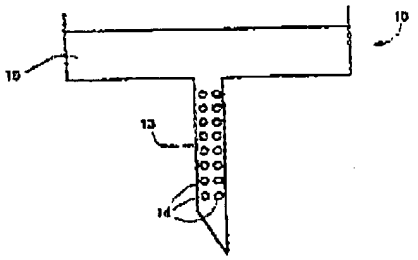
The Examiner has objected to the specification as evoking means-plus-function language to define the invention in Claims 40-49, specifically Claim 40 (means for limiting) and Claims 46-47 (pressure generating means). Applicant respectfully submits that the cancellation of Claims 40-49 without prejudice renders the objections of the

present application moot. Applicants respectfully request that the Examiner reconsider and withdraw the above objections of the present application.

Response to 35 U.S.C. §102/103 Rejection

In the Office Action, the Examiner has rejected Claims 1-8, and 40-49 under 35 U.S.C. §102(e) or in the alternative 35 U.S.C. §103(a) over U.S. Pat. No. 6,314,317 to Willis (hereinafter "Willis). As discussed above, Applicants have cancelled Claims 40-49. Applicants respectfully traverse the §102 rejection. Willis discloses a drug delivery device having a member (13) needle-like device having a plurality of pores (14). The Examiner contends that FIG. 2 and Col 6, Lines 50-54 of Willis anticipate the Applicants' invention. Although the drawing in FIG. 2 of Willis may appear to show side ports of the Applicant's invention, a closer reading of Willis shows that the pores of Willis **are not continuously open to flow**. Moreover, the pores (14) of Willis are designed to be implemented at high densities, that is, an extremely large number of pores per unit area, which would impede flow. FIG. 2 of Willis has been reproduced with annotations below for the Examiner's convenience:

FIG. 2



Willis FIG.2

0 Microneedles including an interface region and a shaft having a microflow channel therein can be used and are described in, for example, U.S. Pat. No. 5,855,801, which is hereby incorporated herein by reference.
B. The Electroactive Polymer

Willis Column 6 Lines 50-54

To support a rejection of a claim under 35 U.S.C. § 102, it must be shown that each element of the claim is found, either expressly described or under principles of inherency, in a single prior art reference. In addition, the prior art reference must disclose the limitations of the claimed invention "without any need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference." It is axiomatic that anticipation of a claim under § 102 can be found only if the prior art reference discloses each and every element of the claim. Claim 1

includes a side port, a specified pressure range, and a prescribed penetration depth, with an outlet open for continuous flow. Therefore, for Willis to anticipate the claims; Willis must disclose each of the above noted elements. Moreover, Willis contains neither teaching nor suggestion of a side ported needle of the type as now recited in Applicants' amended claims for delivery to the skin at low pressures. Furthermore, Willis contains neither teaching nor suggestion of an open end used in conjunction with a side port needle of the as recited in Applicants' Claims 5 and 6. Thus, applicants respectfully submit that the Examiner's §102 rejection of Claims 1-9 as anticipated by Willis is no longer tenable, and respectfully request withdrawal of that rejection.

In the Office Action, the Examiner has rejected Claims 1-8, and 40-49 under 35 U.S.C. §103(a) as unpatentable over Willis. As discussed above, Applicants have cancelled Claims 40-49. As discussed in the previous response, Willis is a system for subcutaneous injection. Specifically, the pores (14) of Willis are designed to be placed in the patient's subcutaneous tissue (Willis Col 4, Lines 55-56).Willis is silent as to the both the general and precise dimensions of the needles to effect delivery to the skin (intradermally and/or epidermally). In fact, the pore size and location of Willis is selected by the ability to coat the pore with an electroactive polymer. In turn, this allows the pores of Willis to be switchable to facilitate regulation of flow, which creates an additional pressure head, which may be presumed to add to the pressures of delivery to the skin in the use of the Willis device. In contrast, the Applicants' side ports are continuously open as recited in presently amended Claim 1. Thus, Willis provides no motivation to modify the switchable pores of Willis to the continuously open side ports of the Applicants' claimed invention. The Examiner should note, according to MPEP§2143.01 Section III, that the mere fact that references can be modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination or modification. *In re Mills, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990.)* Although a prior art device may be capable of being modified to run the way the apparatus is claimed, there must be a suggestion or motivation in the reference to do so.. See also *In re Fritch, 972 F.2d 1260, 23 USPQ2d 1780 (Fed. Cir. 1992).*

On page 4 of the Office Action, the Examiner contends "*the various ranges taught by the applicant, and clearly disclosed and encompassed by Willis, would be clearly understood by someone of ordinary skill in the art. Therefore it would have been*

obvious to one of ordinary skill in the art at the time of the invention was made to modify the device of Willis to vary the various dimensions as set forth in the claims since Willis teaches that the various ranges can be changed and/or varied." The modifications of Willis would be in the context of electropolymer coated ports. The Examiner has failed to point to any disclosure or suggestion in Willis, merely citing examples directed to the modification of Willis. In fact, Willis neither teaches nor suggests any range of dimensions for pore sizes that overlap with the Applicants' side port range, or the placement of the side port for delivery into the skin. The Examiner has not established, *why* the modifications of Willis' pores would have suggested the claimed shape and dimensions of the Applicants' side ports. For the foregoing reasons, the Examiner has not established a prima facie case of obviousness in view of the modification of Willis for Claims 1-9.

Furthermore, it would not have been obvious to simply adapt or modify the micro-level device of Willis having an electropolymer coated pore needle device with micron sized holes to the Applicants' claimed invention. Willis does not teach or disclose advantages as mentioned above *inter alia* pressure reduction and the dimensions and structure of needle devices as in the instant invention cannot be achieved by Willis alone or in a modified form; therefore, the invention is non-obvious over the teachings of Willis. For all the reasons stated above, the modification of Willis does not produce the instant invention as claimed. Furthermore, the Applicants contend the record does not appear to establish the requisite motivation for modifying Willis, as obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. In the case of the present application, the suggestion to modify Willis is not present

New Claims

New Claims 50-59 have been added to further define aspects of the invention, which are fully supported by the instant specification. Specifically, the new claims incorporate limitations of the gage of the needle, the type of penetration and the amount of fluid delivered. Accordingly, no new matter has been added. New independent Claim

57 has similar elements and structure as original Claim 1 but in addition recites structural limitations not recited in original Claim 1, *inter alia* the dimensional constraints of the needle and side port outlet size. For all of the reasons discussed previously, none of the references, alone or in combination, teach or suggest the device as outlined in Claim 57. Without discussing each in detail, it will be appreciated that the claims depending directly or indirectly from Claim 57 recite additional features that are not taught or suggested by the prior art (Claims 58-59).

Conclusion

In view of the Remarks above, applicant respectfully submits that Claims 1-9 and 50-59 are clearly in condition for allowance, and respectfully requests that the Examiner earnestly reconsider the objections and rejections of the present application. Applicant hereby authorizes the Commissioner to charge the fees necessary in connection with this Response, the three-month extension, and any other fees necessary in connection with this application, as well as, credit any overpayment to Deposit Account Number 02-1666.

In light of the above amendments and remarks, Applicant respectfully requests that the Examiner enter the amendments and consider the remarks made herein. Consideration and prompt allowance of the claims are respectfully submitted.

Any questions concerning this application or amendment may be directed to the undersigned agent of applicant.

Respectfully submitted,

By: _____

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